

REMARKS

The Patent Office asserts that two restriction requirements are required in this case, one superimposed upon the other. The first restricts the claims based upon the products and methods claimed and the second based solely upon the SEQ IDs recited in the claims. However, at least some of the claims are related in that, for example, they encompass both methods for using the recited peptide or polypeptide and the polypeptides or peptides themselves. Under the PTO's Training Materials and procedures, these groups of claims should be joined and examined together. *See, for example*, M.P.E.P. § 821.04 and 1184 O.G. 86, March 26, 1996. The subject matter of Groups I and V, for example, share this relationship and should be examined together. Other similarly related subject matter should be examined to gather also.

In addition, applicants respectfully submit that the Patent Office's own rules for examination practice clearly indicate that more than one SEQ ID NO should be examined. At M.P.E.P. § 803.04, the following text appears:

It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined. Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together.

In some exceptional cases, the complex nature of the claimed material, for example a protein amino acid sequence reciting three-dimensional folds, may necessitate that the reasonable number of sequences to be selected be less than ten.

These rules clearly direct that at least ten different sequences can be and should be examined together. They also clearly show that "independent and distinct" sequences are not the type of independent and distinct inventions that must be examined separately. Paper No. 10 assumes the opposite. Reconsideration in light of the applicable rules, as quoted above, is respectfully requested.

The Patent Office has also not addressed or provided any evidence or reasoning on the applicability of the "exceptional case" here. As noted in the rule quoted above, certain complexity requirements must be met for cases where the ten nucleotide sequence examination rule is not employed. The Patent Office has not asserted that this case is exceptional or provided any evidence that it might be. Thus, applicants submit that the above-quoted rule applies to this application and the Patent Office should apply it in this application.

Finally, Paper No. 10 fails to satisfy the requirement for showing a serious burden in examining the claims and even the sequences together. Without a serious burden, the requirement for restriction should be withdrawn. *See* M.P.E.P. § 803. According to the Patent Office rules quoted above, there is no burden in searching at least ten different sequences. In the face of this clear indication that at least ten sequences should be examined together, the Patent Office has not shown why there is a burden in searching all the claims in Paper No. 10. None of the reasons given for the restriction requirement implicate a serious burden.

No additional fees are believed to be required for entry and consideration of this paper. However, should the U.S. Patent and Trademark Office determine that additional fees are due to keep this application pending or to enter this paper, the Commissioner is hereby authorized to charge Deposit Account No. 50-1129 for any fees and petitions necessary.

Respectfully submitted,
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